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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Tenax Therapeutics, Inc. (TENX-NASDAQ)

Undiscovered Gem

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $4.00 per share. We apply a 15% probability of eventual sales of levosimendan in the United States.

Current Price (5/18/20)	$1.03
Valuation	**$4.00**

OUTLOOK

Tenax has licensed the *calcium sensitizer/K-ATP activator* Levosimendan and is currently pursuing approval for an indication in Group 2 Pulmonary Hypertension in the US and Canada with the HELP trial. The drug has been approved in over 60 countries with 35 published trials supporting its safety and efficacy and has over 1 million patient exposures.

In January 2018 Tenax announced a new indication for Levo and met with the FDA in April to confirm trial design. This indication has a target population of between 1.5 and 2.0 million patients in the US with no existing treatment therapy. TENX activated its first site for PH-HFpEF in November 2018. Based on development for similar indications, the duration for Ph2 and Ph3 is expected to yield registrational data by 2023, followed by a 2024 launch of Levo in PH-HFpEF.

Levo has a ~20 year history of use in Europe with a substantial volume of literature supporting its safety and efficacy. Given the body of research supporting the use of Levo in pulmonary hypertension and its inotropic and lusitropic effects, there is sufficient support to justify a Ph2 trial in PH-HFpEF. Additionally, this is a materially sized market with no current therapy, which provides substantial pricing and penetration opportunity.

SUMMARY DATA

52-Week High	**$1.68**
52-Week Low	**$0.25**
One-Year Return (%)	**-24.1**
Beta	**1.8**
Average Daily Volume (sh)	**240,444**
Shares Outstanding (mil)	**9.2**
Market Capitalization ($mil)	**$9.5**
Short Interest Ratio (days)	**0.31**
Institutional Ownership (%)	**21.8**
Insider Ownership (%)	**0.4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**N/A**
P/E using 2020 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.33 A	-$0.28 A	-$0.33 A	-$0.41 A	-$1.35 A
2020	-$0.38 A	-$0.27 E	-$0.13 E	-$0.12 E	-$0.77 E
2021					-$1.27 E
2022					-$1.84 E

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WHAT'S NEW

First Quarter 2020 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) completed enrollment of its **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP) and announced that the last patient has completed their final visit as of April 9, 2020. The 37-patient open-label trial achieved an 84% initial response rate for screened patients and is expected to finish analyzing data and report topline results in 2Q:20.

We are very excited and optimistic about Tenax prospects for Levisimendan. Early evidence shows that Levisimendan can provide a statistically significant material benefit, shown by the 37 of 44 patients who achieved a reduction in pulmonary capillary wedge pressure (PCWP) of 7.8 mmHg, an average reduction in pulmonary arterial pressure (mPAP) of 4.8mmHg, an average reduction in right atrial pressure (RAP) of 5.3 mmHg, and an average increase in cardiac output (CO) of 0.4 liters/min. The improvements were generated during the open-label lead-in phase and achieved statistical significance, with the exception of cardiac output. Individuals with Group 2 pulmonary hypertension comprise a **large population, many multiples greater than the $5 billion in revenue Group 1.** We see a substantial opportunity for commercial success for Levosimendan as **there are no other treatments available for this condition**. While we are a long way from approval, the **reward to risk is dramatically positive** on a probability adjusted basis.

On May 15th, Tenax filed its 1Q:20 Form 10-Q with the SEC. No revenues were reported in the period and operating expenses totaled $2.7 million. Net loss per share was ($0.38). First quarter research and development costs of $1.3 million rose 178% from the $0.5 million spent in the comparable period reflecting screening and enrolling by the HELP trial. General and administrative expenses totaled $1.3 million, up 12%. Increased legal fees, investor relations costs and insurance costs were partially offset by other administrative fees. Net loss for the period was ($8.4) million or ($1.35) per share.

Cash and securities balance was $4.9 million as of March 31, 2020 and cash burn totaled ($2.7) million for 1Q:20. The company continues with no debt. We anticipate a decrease in expenses for the balance of 2020 as the HELP trial undergoes finalization, data lock up and data analysis and papers are drafted for conference presentation.

The HELP Trial

In November 2018 Tenax announced the activation of the first clinical research site for the PH-HFpEF HELP trial at Stanford University School of Medicine. In March 2019, the first of what would eventually be 37[1] patients was enrolled in the trial at 10 sites across the US. By March 12th 2020 all patients had been enrolled and by April 9th the final patient completed the final visit. Top line data is expected to be reported before the end of the second quarter as the company now finalizes the trial and conducts data lock up and analysis. Ample data were collected during the study which will provide fertile ground for researchers ro provide analysis. We anticipate publication at conferences in the latter half of the year. Tenax management will develop its own materials and Phase III trial design to present at the end-of-Phase II meeting with the FDA prior to year end. The HELP study reported zero drug-related serious adverse events. Two of the 37 patients did not complete the study.

A Phase III trial may begin in 2021, assuming the HELP trial results are favorable. Its design is highly dependent on the strength of signal generated by Phase II. A rough estimate of time, cost and size of the registrational trial range from 18 to 36 months, $30 to $50 million and 200 to 300 patients. While none of these estimates have been confirmed by the company, we believe they are reasonable based on the likely outcome of a successful Phase II.

HELP Trial Design

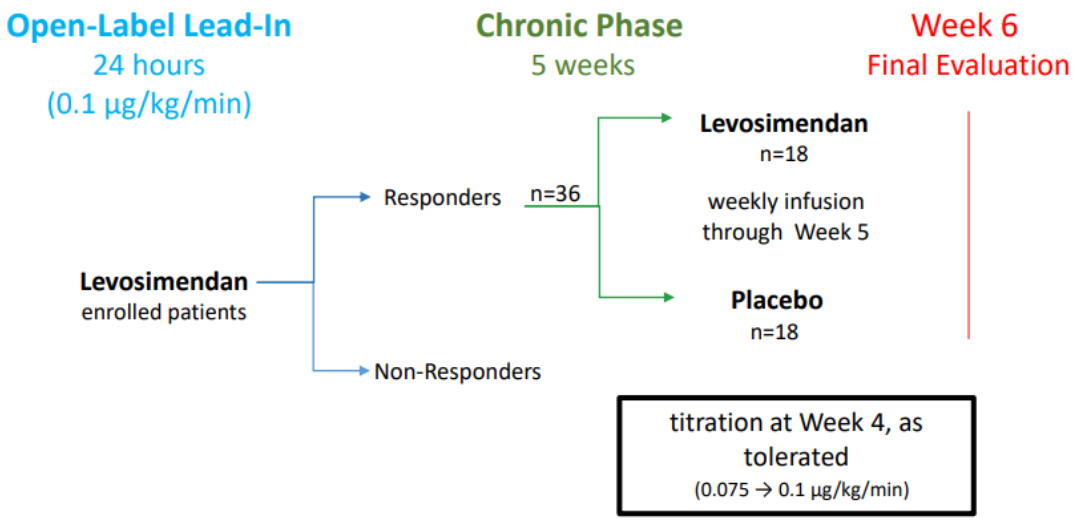
Required thresholds for inclusion in the trial call for patients with pulmonary arterial pressure (PAP) equal to or greater than 35, a pulmonary capillary wedge pressure (PCWP) equal to or greater than 20, a cardiac index (CI) of less than or equal to 2.2, a left ventricular ejection fraction (LVEF) of over 40 and NYHA Class IIb or III. The primary endpoints of the study are:

- Change from baseline PCWP with bicycle exercise (25 watts) at Week 6
- Detect a greater than or equal to 4.8 mmHg change in PCWP from baseline

[1] The trial originally targeted 36 patients.

Expected secondary endpoints include: change in resting PCWP under a variety of conditions, change in resting & stressed CI, change in pulmonary vascular resistance (PVR) at rest & under stress, global assessment at week six based on the Likert scale and length of exercise period and a physician's assessment of functional class and clinical events, including death and hospitalizations.

Exhibit I – Phase II Study Design[2]

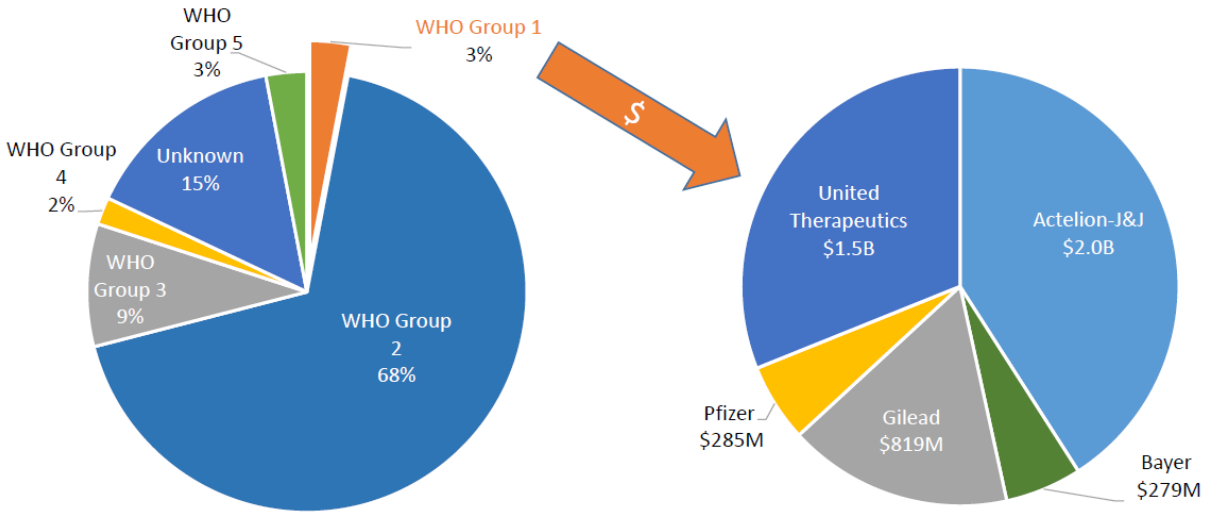


The HELP study uses a 24-hour, once-per-week, at-home intravenous infusion regimen of between 0.075 to 0.100 µm/kg/min using an ambulatory infusion pump. The home-based approach allows for a less frequent but longer session infusion regimen as compared with what would be practical in a hospital setting.

Update on PH-HFpEF Unmet Need

Tenax provided a review of the unmet need in its latest corporate presentation dated February 2020. The review reminded investors of the over two million PH-HFpEF patients in the United States who lack treatment and suffer from high mortality and a poor quality of life. There are five groups of pulmonary hypertension and only Group 1 has approved treatments. Group 1 comprises 3% of the total population of PH, while Group 2 makes up 68%. Group 2 is the population that Tenax is pursuing with its Levosimendan trials.

Exhibit II – PH Prevalence and Market Size[3]



[2] Source: Tenax September 2019 Investor Presentation.
https://s3.amazonaws.com/cdn.irdirect.net/PIR/942/3392/TENX%20Investor%20Presentation%20Jan%202019.pdf
[3] Source:Tenax Corporate Presentation,February 2020. Pulmonary Hypertension Association Strange G, *et al* Heart. 2012;98(24):1805 11

Several other studies have been launched in PH-HFpEF using a variety of products including Bosentan, Macitentan and Riociguat. None of these trials demonstrated an effective treatment for the condition and further pursuit for these candidates in this indication was abandoned.

Exhibit III – Trials Conducted for PH-HFpEF[4]

Trial	BADDHY	MELODY	DILATE	HELP
Sponsor	Actelion/J&J	Actelion/J&J	Bayer	Tenax
Product	Bosentan	Macitentan	Riocigaut	Levosimendan
Approved Indication	PAH	PAH	PAH/CETPH	ADHF-Outside US
Patients (#)	20	63	39	36
Design	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled
Study Duration	12 weeks	12 weeks	Single Dose	6 weeks
MOA	Pulmonary Vasodilator	Pulmonary Vasodilator	Pulmonary Vasodilator	Lusitrope Inotrope Vasodilator
Result	Ineffective, Stopped early	Ineffective, Fluid retention	Ineffective	Ongoing-TBD

Milestones

- Enroll First Patient – March 2019
- Full Enrollment – 1Q:20
- Last Patient, Last Visit – April 2020
- Topline data – 2Q:20
- Presentation of data at conference – Fall 2020
- End of Phase II Meeting with FDA – 2H:20
- Launch Phase III – 2021

Summary

Now that the HELP trial has completed the last visit for the last patient, management has guided toward a late second quarter 2020 topline readout. Initial response for predefined responders was an average reduction of 7.8 mmHg PCWP, which along with other initial collected data make a strong case for trial success. Based on the research and analysis included in our initiation, we believe PH-HFpEF patients will benefit from Levosimendan's mechanism of action and clinical trials can be pursued with a reasonable cost and time commitment. The indication is also in an area with no other approved treatments. Market size is sizeable and with no other approved therapy available, pricing should be strong and penetration high. We maintain our valuation at $4.00 per share.

[4] Source: Tenax Corporate Presentation, February 2020.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Research and development	$3.5	$1.3	$1.2	$0.5	$0.5	$3.5	$10.6	$11.7
General & administration	$5.1	$1.3	$1.2	$1.3	$1.3	$5.1	$5.3	$5.5
Income from operations	($8.6)	($2.7)	($2.4)	($1.8)	($1.8)	($8.7)	($15.9)	($17.1)
Operating Margin	-					-	-	-
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.2)	($0.0)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($8.4)	($2.7)	($2.4)	($1.8)	($1.8)	($8.7)	($15.9)	($17.1)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$15.9	$34.3
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*	*200%*
Net Income	**($8.4)**	**($2.7)**	**($2.4)**	**($1.8)**	**($1.8)**	**($8.7)**	**($31.8)**	**($51.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.35)**	**($0.38)**	**($0.27)**	**($0.13)**	**($0.12)**	**($0.77)**	**($1.27)**	**($1.84)**
YOY Growth	*-69%*	*15%*	*-3%*	*-62%*	*-70%*	*-43%*	*65%*	*44%*
Basic Shares Outstanding	6.20	6.97	9.00	14.40	14.60	11.24	25.00	28.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Share Price Chart



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